April 5, 2006

Edwin L. Mongan, III
Manager, Environmental Stewardship
E.I. du Pont de Nemours & Company, Inc.
1007 Market Street
DuPont 6082
Wilmington, DE 19898

Dear Mr. Mongan:

The Office of Pollution Prevention and Toxics is transmitting EPA's comments on the robust summaries and test plan for Dichloroacetyl Chloride posted on the ChemRTK HPV Challenge Program Web site on October 18, 2004. I commend E.I. du Pont de Nemours & Company, Inc. for its commitment to the HPV Challenge Program.

EPA reviews test plans and robust summaries to determine whether the reported data and test plans will provide the data necessary to adequately characterize each SIDS endpoint. On its Challenge Web site, EPA has provided guidance for determining the adequacy of data and preparing test plans used to prioritize chemicals for further work.

EPA will post this letter and the enclosed comments on the HPV Challenge Web site within the next few days. As noted in the comments, we ask that DuPont advise the Agency, within 60 days of this posting on the Web site, of any modifications to its submission. Please send any electronic revisions or comments to the following e-mail addresses: oppt.ncic@epa.gov and chem.rtk@epa.gov.

If you have any questions about this response, please contact Mark Townsend, Chief of the HPV Chemicals Branch, at 202-564-8617. Submit questions about the HPV Challenge Program through the "Contact Us" link on the HPV Challenge Program Web site pages or through the TSCA Assistance Information Service (TSCA Hotline) at (202) 554-1404. The TSCA Hotline can also be reached by e-mail at tsca-hotline@epa.gov.

I thank you for your submission and look forward to your continued participation in the HPV Challenge Program.

Sincerely,

/S/

Oscar Hernandez, Director
Risk Assessment Division

Enclosure
cc: W. Penberthy
J. Willis

EPA Comments on Chemical RTK HPV Challenge Submission:
Dichloroacetyl Chloride

Summary of EPA Comments

The sponsor, E.I. du Pont de Nemours and Company, submitted a test plan and robust summaries to EPA for dichloroacetyl chloride (DCAC, CAS No. 79-36-7) dated September 29, 2004. EPA posted the submission on the ChemRTK HPV Challenge Web site on October 18, 2004. Data were submitted for two related substances: dichloroacetic acid (DCA, CAS No. 79-43-6) and monochloroacetic acid (MCA, CAS No. 79-11-8).

EPA has reviewed this submission and has reached the following conclusions:

1. Analog Justification. The use of DCA, a hydrolysis product of DCAC, is reasonable for all SIDS endpoints. However, the submitter needs to provide an analog justification for MCA for the ecological effects endpoints.

2. Physicochemical Properties. The submitter needs to provide melting point data.

3. Environmental Fate. The submitted data are adequate for the purposes of the HPV Challenge Program.

4. Health Effects. The submitted data for acute, genetic, repeated-dose and developmental toxicity are adequate for the purposes of the HPV Challenge Program. EPA reserves judgement on the reproductive toxicity endpoint pending the receipt of critical data elements. The submitter needs to address deficiencies in the robust summaries.

5. Ecological Effects. EPA reserves judgement on the adequacy of data submitted for all ecological effects endpoints pending submission of an adequate analog justification for and sufficient study details on MCA. The submitter needs to address deficiencies in the robust summaries.

EPA requests that the submitter advise the Agency within 60 days of any modifications to its submission.

EPA Comments on the Dichloroacetyl Chloride Challenge Submission

Analog Justification

1. EPA agrees that DCA is an appropriate analog for DCAC, as DCAC hydrolyzes to DCA in less than one second.

2. The submitter provided ecological effects data for MCA without justifying its use as an analog. For example, the table of physicochemical properties for DCAC and DCA lacks a corresponding column for MCA, and there is no discussion of whether properties and specific available effects data suggest similar ecotoxicological behavior for DCA and MCA.

Test Plan

Physicochemical Properties (melting point, boiling point, vapor pressure, partition coefficient, and water solubility)

The submitted data for boiling point, vapor pressure, partition coefficient, and water solubility are adequate for the purposes of the HPV Challenge Program.

Melting point. The submitted melting point information for DCAC is inadequate for the purposes of the HPV Challenge Program. The submitter states that the melting point of dichloroacetyl chloride is "Not applicable" and provides melting point data for the hydrolysis product, DCA. The submitter needs to provide measured melting point data for DCAC . However, if the melting point is below 0°C, an estimated melting point is adequate for the purposes of the HPV Challenge Program.

Environmental Fate (photodegradation, stability in water, biodegradation and fugacity)

The submitted data for all SIDS endpoints are adequate for the purposes of the HPV Challenge Program.

Health Effects (acute toxicity, repeated-dose toxicity, genetic toxicity, and reproductive/developmental toxicity)

General

The test plan should discuss possible effects from exposure to the concomitant hydrolysis product hydrochloric acid (HCl). This discussion could be limited to the effects observed at concentrations equimolar to those for DCA (or DCAC)(e.g., adding HCl data to the repeated dose effects in Table 6).

Acute toxicity. The dermal LD50 for DCAC, 650 mL/kg, should probably be in µL/kg. This and similar values need to be checked and corrected in the test plan and robust summary (according to the robust summary text the maximum dose was no more than 20 mL/kg).

Reproduction toxicity. EPA reserves judgement on the reproduction toxicity endpoint. The test plan indicates that male reproductive effects were observed in rats and dogs (testes, sperm effects, etc) after exposure to DCA in a 3-month oral toxicity study. If available, data for effects on the female reproductive system need to be extracted from these studies and added to the robust summary in order to adequately address this endpoint.

Ecological Effects (fish, invertebrates, and algae)

EPA reserves judgement on the adequacy of the data submitted for the ecological effects endpoints pending the receipt of more information.

Summaries were provided for toxicity studies of the DCAC hydrolysis product DCA and of the proposed analog MCA. The data for DCA are inadequate because the studies were not consistent with OECD test guidelines (too short or long test durations and non-OECD-recommended aquatic species) and the study details were not sufficient. For the studies using MCA, no justification was provided for their use (see Analog Justification section above), and study details were inadequate.

The test plan states, "It was also possible to use ECOSAR to estimate the acute toxicity of [DCA and MCA]." This is misleading, as in this case ECOSAR underestimated the toxicity by three orders of magnitude. This and related statements should be modified accordingly.

Specific Comments on the Robust Summaries

General

The following comments apply to all the robust summaries provided by the submitter. In general, the robust summaries do not provide sufficient detail. The submitter should consult EPA guidance documents for the preparation of robust summaries (http://www.epa.gov/opptintr/chemrtk/guidocs.htm).

Ecological Effects

MCA

Fish. Missing study details included test substance purity, test concentrations, test conditions (e.g., pH, temperature, dissolved oxygen, water hardness, and total organic carbon (TOC)), control response, statistical methods, and 95% confidence intervals.

Invertebrates. Missing study details included test substance purity, test substance concentrations, test conditions (e.g., pH, temperature, dissolved oxygen, water hardness, and total organic carbon (TOC)), 95% confidence limits, and statistical methods.

Algae. Missing study details included test substance purity, test concentrations, number of replicates per concentration, study conditions (e.g., pH, lighting conditions, and temperature), cell concentrations, control cell growth, whether reported endpoint values were based on nominal or measured concentrations, statistical methods, and 95% confidence limits.

Followup Activity

EPA requests that the submitter advise the Agency within 60 days of any modifications to its submission.